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| - PRI ICA TIONI NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|---------------------|----------------------|---------------------|------------------|--|
| 09/403,724 | 12/20/1999 | PETER SONDEREGGER | 030708-035 | 7613 | |
| 21839 7590 01/14/2002 BURNS DOANE SWECKER & MATHIS L L P POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404 | | | EXAMINER | | |
| | | | CHERNYSHEV, OLGA N | | |
| ALLAANDIC | 111, 111 22210 1111 | | ART UNIT | PAPER NUMBER | |
| | | | 1646 | | |

DATE MAILED: 01/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | | Applicant(s) | | | |
|---|--|---------------------------------|------------------|--|--|--|--|
| Office Action Summary | | 09/403,724 | • | SONDEREGGER, PETER | | | |
| | | Examiner | | Art Unit | | | |
| | | Olga N. Chernys | hev | 1646 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | | |
| Period for | r Reply | EDI VIQ SET TO EX | DIRE 3 MONTH | 'S) FROM | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status 1)□ | Responsive to communication(s) filed on | · | | | | | |
| 2a)⊠ | · | This action is non-f | inal. | | | | |
| 3) | The state of the s | | | | | | |
| Dispositi | on of Claims | | | | | | |
| 4)🛛 | Claim(s) 16,19,31 and 32 is/are pending | in the application. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) | Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>16, 19, 31, 32</u> is/are rejected. | | | | | | | |
| | Claim(s) is/are objected to. | | | | | | |
| 8)□ | Claim(s) are subject to restriction a | and/or election require | ement. | | | | |
| Applicat | ion Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12)☐ The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority | under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a) All b) Some * c) None of: | | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachme | | | | | | | |
| 1) Not | ice of References Cited (PTO-892) ice of Draftsperson's Patent Drawing Review (PTO-9 ormation Disclosure Statement(s) (PTO-1449) Paper | 4) [948) 5) [No(s) 6) [| Notice of Inform | ary (PTO-413) Paper No(s) al Patent Application (PTO-152) | | | |
| | | | | | | | |

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DETAILED ACTION

Response to Amendment

- 1. Claims 16 and 19 have been amended and claims 31 and 32 have been added as requested in the amendment of Paper No.12, filed on October 26, 2001. Claims 16, 19, 31 and 32 are pending in the instant application.
- 2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action
- 3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 4. Applicant's arguments filed on October 26, 2001 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16, 19, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Claims 16, 19, 31 and 32 are directed to neurotrypsin and a method of use of the neurotrypsin. However, the instant specification does not provide any guidance needed to produce a neurotrypsin, which is a polypeptide, while identifying it by sequence of SEQ ID NO:1, which is a nucleic acid sequence. It would require undue experimentation for one skilled in the art to discover how to make and use the invention as currently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 6. Claims 16, 19, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which Applicant(s) regard as their invention. Evidence that claims 16, 19, 31 and 32 fail(s) to correspond in scope with that which Applicant(s) regard as the invention can be found in Paper No. 12 filed October 26, 2001. In that paper, Applicant has stated that "The coded peptide of the compound of the formula I (SEQ ID NO:1) has a length of 875 amino acids" (page 2 of the Amendment), and this statement indicates that the invention is different from what is defined in the claim(s) because SEQ ID NO:1 is not an amino acid sequence but a nucleotide sequence according to the sequence listing provided by Applicant.
- 7. Claims 19, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19, 31 and 32 are indefinite and ambiguous because the claims are directed to a method without any method steps, such omission amounting in incompletion of the claimed invention. See MPEP § 2172.01.

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Conclusion

8. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

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Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. OC January 3, 2002

JOHN ULM PRIMARY EXAMINER GROUP 1800